K062686 1/1

510(k) Summary
Universal Spinal Anterior Locking Plate System

OCT - 5 2006

This safety and effectiveness summary for the Universal Spinal Anterior Locking Plate System is provided as required per Section 513(i)(3) of the Food, Drug and Cosmetic Act.

Date Prepared: September 4, 2006

1. **Submitter:**

Advanced Spine Technology, Inc.
457 Mariposa St.
San Francisco, CA 94107
Telephone: 415-241-2400

Contact Person:
J.D. Webb
The OrthoMedix Group, Inc.
1001 Oakwood Blvd
Round Rock, TX 78681
Telephone: 512-388-0199

2. **Trade name:** Universal Spinal Anterior Locking Plate System
   Common Name: anterior spinal plate
   Classification Name: Spinal intervertebral body fixation orthosis per CRF 888.3060
   KWQ

3. **Predicate or legally marketed devices which are substantially equivalent:**
   - The Universal Spinal Anterior (USA) Locking Plate system is a modification to the Amset Locking Plate (K905023).

4. **Description of the device:**
   The USA Locking Plate System consists of a multiple sized plates and screws. All components are fabricated from titanium alloy (Ti-6Al-4V) that conforms to ASTM F136. Fixation is provided by inserting screws through holes in the plate into the vertebral bodies of the thoraco-lumbar and lumbar spine. The bone plates offer slotted and round holes that allow the bone screws to be located and securely seated in various positions. There are two plate configurations available: the straight locking plate and the narrow locking plate. The screws include the universal locking screw, the self locking screw and the cancellous locking screw.

5. **Intended Use:**
   The Universal Spinal Anterior Locking Plate System is intended for anterior/anterolateral fixation for the following indications:

   - degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies);
   - spondylolisthesis;
   - trauma (i.e., fracture or dislocation);
   - spinal stenosis;
   - curvatures (i.e., scoliosis, kyphosis, and/or lordosis);
   - tumor;
   - pseudoarthrosis;
   - and failed previous fusion.

   This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

6. **Comparison of the technological characteristics of the device to predicate and legally marketed devices:**
   The design and indications are similar. The main difference is the change of material from 316L stainless steel to Ti-6Al-4V titanium alloy.

7. **Summary of Nonclincal Tests**
   Engineering analyses show that the maximum allowable loads for the USA straight and narrow plates are greater than the predicate plate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 5 2006

Advanced Spine Technology, Inc
% Mr. J.D. Webb
The OrthoMedix Group, Inc.
1001 Oakwood Boulevard
Round Rock, Texas 78681

Re: K062686
Trade/Device Name: Universal Spinal Anterior Locking Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: September 4, 2006
Received: September 8, 2006

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, and Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Universal Spinal Anterior Locking Plate System

Indications for Use:

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- degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies);
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- pseudoarthrosis;
- and failed previous fusion.

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062686